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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,046	01/17/2006	Kristen E. Belmonte	PU60398	3933

23347 7590 12/02/2008

GLAXOSMITHKLINE  
CORPORATE INTELLECTUAL PROPERTY, MAI B482  
FIVE MOORE DR., PO BOX 13398  
RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER
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RAHMANI, NILOOFAR

ART UNIT	PAPER NUMBER
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1625

NOTIFICATION DATE	DELIVERY MODE
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12/02/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USCIPRTP@GSK.COM  
LAURA.M.MCCULLEN@GSK.COM  
JULIE.D.MCFALLS@GSK.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,046	<b>Applicant(s)</b> BELMONTE ET AL.	
	<b>Examiner</b> NILOOFAR RAHMANI	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/10/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Claims 1-4, 6-20 are pending in the instant application and claim 5 is cancelled in the instant application.
2. The rejection of claims 1-4 under 103(a) over Yu et al., Yaoxue Xuebao, 1983, 18(10), 766-74 and Ran et al., Yaoxue Xuebao, 1984, 19(5), 361-6 and Zhang et al., Yaoxue Xuebao, 1985, 20(10), 752-8 and Wu et al., Zhongguo Yaowu Huaxue Zazhi, 1993, 3(1), 23-6 and Zirkle et al., Journal of medicinal & Pharmaceutical chemistry, 1962, 5, 341-56 are withdrawn in view of applicants amendment and argument in paper dated on 09/22/2008.
3. The rejection of claims 1-13 under 112, first paragraph, as failing to comply with the enablement requirement is maintained for reason of record. Applicants have not argued in paper dated on 09/22/2008. Therefore, the rejection is maintained for the reason of record.
4. The rejection of claims 6-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reason of record. Applicants argued that Muscarinic antagonists have known for many decades. There are large numbers of patents granted by the USPTO on Muscarinic antagonists. One of skill in the art would not question the claimed utility of the compounds described and claimed herein. It is examiner's position that applicants provide no guidance or examples for using a compound of formula (I) could treat any and all known or unknown diseases. nor does

applicants identify what disease are treatable by therapeutically effective amount of a compound of formula (I).

**5. New Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 20 are rejected under 103(a) as being unpatentable over Zirkle et al., Journal of Medicinal & Pharmaceutical Chemistry, 1962, Vol. 5, pages 341-56.

Determination of the scope and content of the prior art (MPEP §2141.01)

Zirkle et al. disclosed analogous compounds, which from the STN search are

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**RN** 102924-25-4

**CN** 8-Azoniabicyclo[3.2.1]octane, 3-(2,2-di-2-thienylethenyl)-8,8-dimethyl-,

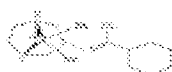
bromide,



•••

**RN** 106801-38-1

**CN** 3a-(b-Cyclohexylstyryl)-8-methyltropanium bromide



•••

**RN** 107422-05-9

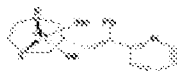
**CN** 8-Azoniabicyclo[3.2.1]octane, 8,8-dimethyl-3-[2-phenyl-2-(2-thienyl)ethenyl]-, bromide.



•••

**RN** 107894-96-2

**CN** 8-Azoniabicyclo[3.2.1]octane, 8,8-dimethyl-3-[2-phenyl-2-(2-pyridinyl)ethenyl]-, bromide,



•••

**RN** 108042-35-9

**CN** 8-Azoniabicyclo[3.2.1]octane, 3-(2,2-diphenylethenyl)-8,8-dimethyl-, bromide,



•••

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that the instant claims claimed a pharmaceutical composition for dry powder inhalation on the respiratory tract of a human of the prior art compounds.

*Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)*

One having ordinary skill in the art would be motivated to modify the compounds of Zirkle et al. to obtain the instant claims. The claim would have been obvious because a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

**6.** Claims 1-4 and 20 are rejected under 103(a) as being unpatentable over Zirkle et al., US 2800482.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Zirkle et al. disclosed analogous compounds, which from the STN search are

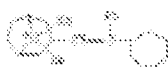
**RN** 110377-10-1

**CN** 3-(2,2-Di-2-thienylvinyl)-8-methyltropanium bromide



**RN** 119040-93-6

**CN** 3-(p-Cyclohexylstyryl)-8-methyltropanium bromide



Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that the instant claims claimed a pharmaceutical composition for dry powder inhalation on the respiratory tract of a human of the prior art compounds.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the compounds of Zirkle et al. to obtain the instant claims. The claim would have been obvious because a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

7. Claims 1-4 and 20 are rejected under 103(a) as being unpatentable over Zirkle et al., US 2800478.

Determination of the scope and content of the prior art (MPEP §2141.01)

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Zirkle et al. disclosed analogous compounds, which from the STN search are

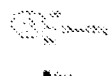
**RN** 110377-10-1

**CN** 3-(2,2-Di-2-thienylvinyl)-8-methyltropanium bromide



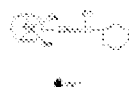
**RN** 118801-08-4

**CN** 3-(2,2-Diphenylvinyl)-8-methyltropanium bromide



**RN** 119040-93-6

**CN** 3-(6-Cyclohexylstyryl)-8-methyltropanium bromide



**RN** 124138-73-4

**CN** 3-(2,2-Diphenylvinyl)-8-methyltropanium p-toluenesulfonate (6Cl)



Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art compounds is that the instant claims claimed a pharmaceutical composition for dry powder inhalation on the respiratory tract of a human of the prior art compounds.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the compounds of Zirkle et al. to obtain the instant claims. The claim would have



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been obvious because a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**8.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/NILOOFAR RAHMANI/

11/21/2008

/D. Margaret Seaman/

Primary Examiner, Art Unit 1625